Biotech Daily

Friday July 8, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MEDICAL DEVELOPMENTS UP 12%;**
- IMUGENE DOWN 4%

*** DR BOREHAM'S CRUCIBLE: EMVISION MEDICAL DEVICES**

*** BREAKTHROUGH VICTORIA UNDISCLOSED GRANT TO SEER MEDICAL**

*** NOVA EYE GLAUCOMA SALES UP 0.5% TO $13.1m**

*** FIREBRICK: TGA CONFIRMS NASODINE REJECTION**

*** NEUROTECH: '93% IMPROVED' IN MARIJUANA FOR AUTISM TRIAL**

*** LUMOS TAKES 'REGULATORY UPDATE' HALT TO SUSPENSION**

*** HAEMALOGIX APPOINTS DR GEOFF NICHOL DIRECTOR**

*** NEUREN APPOINTS DR LIZA SQUIRES US-BASED CMO**

MARKET REPORT

The Australian stock market was up 0.45 percent on Friday July 8, 2022, with the ASX200 up 30.0 points to 6,678.0 points. Twenty-two of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and two were untraded.

Medical Developments was the best, up 20 cents or 11.6 percent to $1.93, with 208,221 shares traded; followed by Paradigm up 11.4 percent to $1.12, with 407,168 shares traded.

Amplia climbed 10 percent; Antisense was up 9.3 percent; Actinogen rose 8.3 percent; Pro Medicus improved 5.2 percent; Clinuvel and Volpara were up more than four percent; Genetic Signatures, Immutep, Next Science and Starpharma were up more than three percent; Atomo, Cynata, Emvision, Nova Eye and Resonance rose more than two percent; Avita, Oncosil, Orthocell, Polynovo and Telix were up by more than one percent; with Cochlear and CSL up by less than one percent.

Imugene led the falls, down one cent or 4.2 percent to 23 cents, with 29.3 million shares traded. Compumedics, Dimerix and Proteomics lost more than three percent; Kazia and Opthea shed more than two percent; Nanosonics and Pharmaxis were down more than one percent; with Neuren and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: EMVISION MEDICAL DEVICES

By TIM BOREHAM

ASX code: EMV

Share price: $1.80

Market cap: $139.7 million

Shares on issue: 77,632,717

Chief executive officer: Dr Ron Weinberger

Board: John Keep (chairman), Dr Weinberger, Scott Kirkland (executive director), Ryan Laws, Geoff Pocock, Tony Keane, Dr Phillip Dubois

Financials (March quarter 2022): receipts $180,000*****, cash outflows $2 million, cash balance $8.5 million, quarters of available funding 4.2

***** Consists of GE Healthcare's final contribution under the Co-operative Research Centres Project

Identifiable major shareholders: Scott Kirkland 5.14%, Ryan Laws 4.6%, Neweconomy Nominees 2.4%, Truebell Capital 2.4%, Uniquest 1.6%.

The world's second biggest killer behind only heart disease and the leading cause of disability, strokes are inflicting a weighty burden on societies - Western and otherwise.

The World Health Organisation says 15 million people suffer a stroke annually, 55,000 in Australia. Five million of them will die and one-third will have a permanent disability.

Victims of the most common ischaemic (blockage) strokes are usually delivered anti-clotting medication at the hospital, but time is crucial and the medicos need to be sure that the stroke is ischaemic rather than haemorrhagic (bleeding: in which case the last thing you want to administer is an anti-clotting drug).

Emvision is seeking to fill the gap with its portable imaging devices which can diagnose a stroke at the bedside in an emergency ward or on the front line: in an ambulance, or even the victim's front door.

At the moment there's no effective treatment by front-line responders (usually paramedics) because they won't know what type of stroke patient they might have.

"We have tried to make the devices as simple as possible, so the information can be transmitted to where it needs to be and analyzed by a suitably qualified clinician," says Emvision chief executive Dr Ron Weinberger.

“They can be used on the ward by nurses with about half a day’s training.”

Having carried out a pilot study with its ‘first generation’ model for use in hospitals, Emvision has launched a 300-person trial aimed at supporting a marketing application to the US Food and Drug Administration (FDA).

In other words - things are happening.

About Emvision

Emvision’s as yet unnamed diagnostic devices - let’s call them Strokebusters - are being developed in partnership with the University of Queensland.

The underlying algorithm and antenna technology was co-invented by Professors Amin Abbosh and Stuart Crozier. The former is a leader in electromagnetic microwave imaging; the latter created the technology central to magnetic resonance imaging (MRI) machines.

Emvision was formed in July 2017 by Scott Kirkland and Ryan Laws, for the purpose of acquiring this tech from the university’s commercialization arm, Uniquest.

Mr Kirkland held senior sales positions at San Francisco’s Quantcast, while Mr Laws has a history of investing in - and arranging funding for - emerging companies.

Dr Weinberger was a key figure behind the ASX-listed device success story Nanosonics, which has commercialized its Trophon sterilizers for body cavity ultrasound probes.

Emvision listed in mid-December 2018, having raised $6 million at 25 cents apiece.

Who ya gonna call? Strokebusters

Based on electromagnetic microwave imaging, the helmet-like Strokebusters can take an image in about 30 seconds and interpret it in less than three minutes. The entire imaging process can be done on a laptop.

Crucially, Emvision doesn’t intend to replace the current stroke imaging methods: computer tomography (CT) or magnetic resonance imaging (MRI) scans.

Emvision’s algorithms create a high-contrast image which is compared to the “ground truth”: the grey-ish pictures from MRI-CT scans.

The added clarity means that not only can new strokes be identified, but also damaged tissue around an old stroke site.

The units are designed to be easily used: a paramedic might conduct the scan and send the images digitally to the hospital ahead of the patient’s arrival.

The devices would be especially useful in remote areas, where access to CT or MRI scanners is limited.

Emvision executive director Scott Kirkland says while CT and MRIs are the gold standard, they are very large machines (600 kilograms or more) and very much stationary.

They can't be used at the bedside to monitor problems such as oedema (brain swelling).

In contrast, the first-generation Strokebusters are about 100 kilograms: "they are easy to fit in with stroke wards or intensive care units where there is limited real estate."

The second-generation units are expected to be as light as 10 kilos and easily carried in a backpack.

The proof is in the pudding

Carried out at Brisbane's Princess Alexandra Hospital, Emvision's foundational trial kicked off in January 2020 and encountered immediate pandemic delays.

Eventually, 50 healthy patients were imaged.

The primary purpose of the trial was to generate data on the electromagnetic scattering effects in the brain, so that the algorithms could be refined.

The imaging showed a clear ability to distinguish between ischemic and haemorrhagic strokes in a way that CT/MRI scan can't.

The company expects to start recruiting for the larger pivotal trial over three sites: Princess Alexandra, Royal Melbourne and Sydney's Liverpool Hospital. Over two legs, the study will focus on pre-validation (focused on usability) and then sensitivity and specificity measures.

The company reports that supply delays impeded delivery of key components, but they have been received, with testing and patient enrolment underway.

The route to market

Given there's no predicate device, Emvision plans to file its FDA application under the de novo (new device) path, rather than the 510k route. Applications to European and Australian regulators are expected thereafter.

Emvision expects the 'gen one' (hospital) devices to sell for $150,000, which compares with $800,000-plus for a CT scanner and many millions for an MRI machine.

The company expects to offer a rental/subscription option to the more capital-constrained healing houses.

The company should also generate healthy revenues from the consumables: mainly the single use, $20 a pop, flexible cap worn under the helmet to improve signaling.

Mr Kirkland says the first-generation model “has the potential” to be in 10,200 US sites, but the company is focusing on 1,600 comprehensive stroke units.

Emvision is keeping mum on distribution opportunities, but as one would expect it’s been chatting with the likes of GE Healthcare, Siemens and Philips.

The company is particularly close to GE Healthcare, given it was a participant partner in a $2.6 million Federal Cooperative Research Centres Project grant awarded in 2017.

Talking from personal experience, Dr Weinberger says life science companies often make the “big mistake” off giving away global exclusive rights.

“There is a lot of glamour with these big companies but there is often a lack of understanding about … what their motivations are relative to yours.”

Finances and performance

The best money is free money and Emvision has done well to tap non-dilutive grant funding - $11.2 million in all.

The company has access to funding via Australia’s Medical Research Future Fund (MRFF) program, in partnership with the Australian Stroke Alliance (ASA),

At the end of March the company had $8.5 million in cash, as well as $6.2 million of untapped ASA funding (the company received $600,000 in late June).

In May 2022, Emvision was awarded a $5 million Federal Modern Manufacturing Initiative Grant. The funds can be used for late-stage trials, first production runs and such: anything that kick-starts production.

“In this market, non-dilutive funding is absolutely golden and we’re now working through the details of the grant,” Mr Kirkland says.

Emvision hasn’t raised equity capital since November 2019, when it tapped investors for $4.5 million in a placement at 74 cents.

Dr Weinberger says the trials as “relatively cheap”, with the pilot phase costing about $350,000. In other words, it should have enough dosh to last until the commercial rollout, expected in 2024.

Emvision shares have lost 45 percent of their value over the last year, with the stock trading as low as $1.30 (June 20 2022) from a high of $3.30 (October 2021).

The shares peaked at $4 in November 2020.

Sizing up the ASX peers

We suspect Emvision's top brass is sick of being asked about the company's similarities with Micro-X, which is also developing a portable (x-ray based) stroke detector for front-line use.

Emvision says a key difference is that its Strokebusters are lighter than Micro-X's device, which would require ambulances to be modified.

Micro-X is developing applications not just for strokes, but for general field screening, airport baggage screening and bomb disposal. Some of its units are being used in the Ukraine.

Meanwhile the stroke-focused Argenica Therapeutics listed in June last year ago on the back of its drug candidate to treat brain cell death in the first instance.

Argenica notes there are no marketed, safe early intervention therapies capable of protecting the brain from damage following stroke.

While Micro-X shares have wilted - probably unfairly - Argenica shares are more than double their 20-cent listing price.

Argenica and Emvision share a common director: the Perth based Geoff Pocock.

Dr Boreham's diagnosis:

Emvision's ultimate ambition is to see the devices installed in every ambulance: the stroke version of the Packer Whackers (the late tycoon funded defibrillators for all New South Wales ambulances after suffering a near fatal heart attack in 1990).

The company expects to take a 'keeping it real' approach to commercialization, focusing on practical aspects such as portability and usability. As part of the MRFF/ASA program the company has consulted extensively with Victorian and New South Wales ambulance end users and the Royal Flying Doctor Service.

As Dr Weinberger acknowledges, there are putative competitors out there, so it's all about value for money.

In the short term, investor attention will focus on the progress of the pivotal trial, the results of which should dribble out progressively.

"As we enrol, we expect to provide plenty of insights and updates throughout the study," promises Mr Kirkland.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But having completed a Nippers swimming certificate, he knows the difference between a backstroke and breaststroke.

VICTORIA GOVERNMENT, BREAKTHROUGH VICTORIA, SEER MEDICAL

The Victoria Government says it will give an undisclosed amount of money to the epilepsy diagnostics and management provider Seer Medical.

A spokesperson for the Victoria Minister for Industry Support and Recovery Ben Carroll told Biotech Daily that the quantity of taxpayer funds being given to Seer Medical through Breakthrough Victoria was “commercial in confidence”.

The Carlton-based Seer Medical said it operated more than 20 clinics across Australia including permanent and visiting clinics.

A media release from the Victoria Government said that Breakthrough Victoria would “invest in Seer Medical, Australia’s largest provider of epilepsy diagnostic services, to support the company’s expansion in overseas markets”.

The media release said that the State Government had previously supported Seer Medical to secure its “global HQ in Victoria”.

The Victoria Government said that Seer was “born out of research and clinical collaborations between the University of Melbourne and [Melbourne’s] St Vincent’s Hospital … [and had] developed an at-home diagnosis and monitoring technology for epilepsy”.

The State Government said that the technology had reduced patient waiting times from six to 18 months to within one to six weeks.

“Seer Medical’s at-home monitoring has diverted more than 179 years of in-patient hospital bed monitoring, freeing-up hospital beds for urgent care and making critical care available to regional patients,” the Victoria Government said.

The media release said that the funding would “help Seer to create up to 225 new Victorian jobs across its headquarters, research and development, manufacturing and production … [allowing] Seer Medical to support growth into overseas markets for its at-home diagnosis and monitoring technology for epilepsy”.

The Government said that Breakthrough Victoria was a Government-owned, independent investment fund manager established to manage the $2 billion Breakthrough Victoria Fund.

Breakthrough Victoria chair John Brumby said that “Breakthrough Victoria’s investment into Seer will mean that Victoria’s economy, health system and patients will improve thanks to the commercialization of Victorian [intellectual property].

Seer Medical is a private company.

NOVA EYE

Nova Eye says its expects glaucoma surgical device sales for the year to June 30, 2022 to be up 0.5 percent to $13.1 million, compared to the previous corresponding period.

Nova Eye said that sales were materially reduced by freight-delayed product bound for Wuhan, China, with a $740,000 delivery not freighted until July 5, 2022, despite being scheduled for collection in June.

The company said that revenue from Germany was up 24 percent, with the US down three percent, and China down 30 percent due to freight delays.

Nova Eye managing-director Tom Spurling said the launch of Itrack Advance in Europe “was an important milestone for our business”.

“Covid-19 presented various challenges, including production and supply issues, as well as restricting access to surgeons,” Mr Spurling said.

“We are now starting to yield the benefits of our investment in Itrack Advance,” Mr Spurling said.

Nova Eye was up half a cent or 2.4 percent to 21.5 cents.

FIREBRICK PHARMA

Firebrick says the Australian Therapeutic Goods Administration has confirmed its decision not to approve Nasodine nasal spray for sale in Australia.

In March, Firebrick said it would appeal against the Australian Therapeutic Goods Administration initial decision not to approve its Betadine-based anti-viral Nasodine nasal spray based on the existing clinical data (BD: Mar 1, 2022).

Today, the company said the basis for the original TGA decision was that "despite having no concerns with the quality or safety of Nasodine the TGA remained unconvinced about the efficacy, based on the first phase III trial not meeting its primary endpoint".

Firebrick's prospectus said that the endpoint for the 260-patient, phase III trial was the impact on nasal symptoms compared to a saline nasal spray placebo, and although Nasodine "achieved a positive benefit of eight percent on that endpoint, but it was not statistically significant and as a result, the phase III trial did not meet its primary endpoint".

Firebrick said while it did not meet its primary endpoint, it did show "statistical significance in reducing overall cold severity …in people with stronger cold symptoms, who started treatment within 24 hours of symptom onset and those with a confirmed viral infection".

Firebrick executive chair Dr Peter Molloy said "ee believe that because overall cold severity was not designated as the 'primary' endpoint, the TGA has discounted the results".

"We strongly believe that the existing clinical data satisfactorily establishes the efficacy of Nasodine in the treatment of the common cold and that the [Administrative Appeals Tribunal] review should lead to an earlier approval of Nasodine," Dr Molloy said.

Firebrick said it intended to file the application to the Administrative Appeals Tribunal

Firebrick was up four cents or 15.4 percent to 30 cents.

NEUROTECH

Neurotech says 13 of 14 patients in its phase I/II trial of NTI164 marijuana for autism spectrum disorder showed symptom improvement after a 28-day course.

Last year, Neurotech said it had begun a 20-subject study of NTI-Dolce medical marijuana for children aged five to 17 years old with autism spectrum disorder (BD: May 5, 2021).

Today, the company said 14 of the hoped-for 20 patients were analyzed and two patients had a "complete or near remission of all symptoms", with 10 patients recording "partial remission of symptoms", and NTI164 was well-tolerated, with no serious adverse events recorded across all doses (5 mg/kg, 10 mg/kg, 15 mg/kg and 20mg/kg).

Neurotech said that the clinical global impression of severity of illness (CGIS) showed "statistical significance at 28 days of treatment" ($p = 0.027$), with parental and carer observations indicating improvement in overall functioning compared to the baseline average severity of illness 4.4 of 7.0, reduced to 3.6 of 7.0 after 28 days of treatment.

Neurotech chair Brian Leedman said that "we cannot underestimate the significance of the results from our world-first landmark trial".

"[Neurotech] is now a significant step closer in the drug development timeline to introducing to the market a treatment option for paediatric [autism spectrum disorder] which is natural, safe and based on the results to date, offers substantial behavioral improvements," Mr Leedman said.

Mr Leedman said the results opened "a new treatment pathway for not just [autism spectrum disorder], but a wide range of neurological disorders such as attention deficit hyperactivity disorder, multiple sclerosis, motor neuron disease, Rett's syndrome and cerebral palsy which are targeted for both [Neurotech] and strategic partner trials".

Neurotech fell half a cent or 6.7 percent to seven cents with 16.8 million shares traded.

LUMOS DIAGNOSTICS

Lumos has taken its July 6 trading halt to a suspension “to prepare a full response to regulatory feedback received in relation to Febridx” (BD: Jul 6, 2022).
Trading will resume on July 11, or on an earlier announcement.
Lumos last traded at 16.5 cents.

HAEMALOGIX

Haemalogix says it has appointed Dr Geoff Nichol as a non-executive director.
Haemalogix said Dr Nichol was most recently the San Rafael, California-based Bio-Marin Pharmaceutical’s chief medical officer and previously was an executive at Sangamo Biosciences, Medarex and Novartis.
The company said Dr Nichol held a Bachelor of Medicine, Bachelor of Surgery from New Zealand’s Otago University and a Master of Business Administration from England’s Warwick University.
Haemalogix is a private company

NEUREN PHARMACEUTICALS

Neuren says it has appointed Dr Liza Squires as its US-based chief medical officer.
Neuren said Dr Squires was a “board certified physician in general pediatrics and neurology with special competence in child neurology”.
The company said that Dr Squires previously worked for Johnson & Johnson, Shire Pharmaceuticals, Lumos Pharma, Aevi Genomic Medicine and Origin Biosciences.
Dr Squires Linkedin page said that she held a Bachelor of Science from the Ann Arbor-based University of Michigan and a Doctor of Medicine from the East Lansing Michigan State University.
Neuren fell two cents or 0.5 percent to $3.90.